

PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115

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Center for Medicaid and State Operations

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Pharmacy Plus Application

The State of Maine, Department of Human Services, proposes an 1115 Demonstration Proposal entitled HMP/D, which will extend pharmacy services and related medical management interventions to Medicare and non-Medicare beneficiaries, whether or not they are eligible for Medicare Savings programs under Medicaid [which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g. Qualified Medicare Beneficiaries (QMBs) and Specified Low-income Medicare Beneficiaries (SLMBs)] and/or adults age 19 and older who are disabled and who are not eligible for full Medicaid benefits.

A. GENERAL DESCRIPTION

This demonstration will extend pharmacy coverage to individuals in a fashion that furthers public, private, and individual fiscal responsibility. Individuals eligible for the proposed program include those who are Medicare beneficiaries, whether or not they are eligible for Medicare Savings programs under Medicaid (which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g. QMBs and SLMBs) and/or people with a disability, who are not eligible for full Medicaid benefits. The proposed program includes pharmacy benefits and coordination or coverage of primary care that complements and assists in the management of the enrollee's pharmacy services.

The demonstration is designed to assist individuals who otherwise would have spent large amounts of money on pharmacy items. The demonstration offers assistance by either providing the pharmaceutical products, by assisting individuals with high premiums/cost sharing for private coverage for pharmacy, or by providing wraparound pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage.

The demonstration provides incentives for individuals with private coverage not to drop the existing coverage in favor of demonstration coverage and adopts competitive private sector approaches to provide more cost effective, modern prescription drug benefits in Medicaid.

Cost sharing in the form of premium, copayment, and deductible responsibilities of the expansion population in this demonstration may be different from normal requirements in Medicaid. Cost sharing may be used to reduce program costs by requiring enrollee payments and encouraging the use of non-brand drugs. Cost sharing models used in Pharmacy Plus may also protect people with most severe illnesses or disabilities by offering “stop-loss” protection against the cumulative impact of copayments and deductibles, or by reducing cost sharing responsibilities on a sliding scale basis. It is an important goal of Pharmacy Plus to utilize private-sector benefit management approaches (such as pharmacy benefit managers, preferred drug lists, prior authorization, pharmacist consultation, and variable enrollee cost sharing) in order to more efficiently and effectively manage pharmaceutical costs and ensure that spending stays within the federal budget neutrality cap. These benefit management approaches may be adopted for some or all of the existing Medicaid population, either which could assist in achieving budget neutrality.

Budget neutrality will be maintained by savings generated from improved access to pharmacy coverage, improved service delivery or medication management, and improved cost-management techniques in pharmacy administration. Consistent with the pharmaceutical focus of Pharmacy Plus, the demonstration does not include non-pharmacy benefit changes (such as reducing Medicaid coverage for other services or reducing coverage for existing Medicaid populations). The challenge posed in Pharmacy Plus is to improve cost-effectiveness through maintaining the health status of individuals and managing medications more effectively.

The budget neutrality ceiling will be a single aggregate budget amount for the demonstration period and the State will be accountable for both expenditure and enrollment growth in the capped population. The capped population will be the impacted State plan eligibility population and the expansion population.

Although the demonstration will incur costs for a new population of individuals, the program is budget neutral for the reasons outlined in this application. The information filled out below describes the individuals eligible for this demonstration, the demonstration benefits and cost sharing, delivery systems, budget neutrality, and the demonstration authority.

Federal financial risk will be capped by the budget neutrality ceiling. The special terms and conditions of demonstration award for this Pharmacy Plus demonstration will specify the aggregate financial ceiling on Federal financial payments for services included in the budget neutrality agreement. The sum of the State’s Medicaid expenditures for the current law population and the drug expansion will not exceed what would have been paid without the demonstration.

The demonstration would operate for 5 years, beginning approximately 10/02.

B. ASSURANCES

Each of the following items are checked to indicate an assurance:

- A. X **Primary care coordination.** The demonstration includes a mechanism to direct demonstration enrollees utilizing services to sources of basic primary health services to ensure access as needed. Such primary care will include, but is not limited to, medical management related to prescription and non-prescription pharmaceutical products. The State assures that coordination of primary care and demonstration services will take place for all enrollees, and that those individuals who do not qualify for a Medicare primary care benefit will have access to primary care services.
- B. X **Benefits, access to services and cost sharing.** The benefits and rights of the State plan eligibility groups, except for restriction to choice of providers as provided for through a section 1115(a)(1) waiver of 1902(a)(23) through Pharmacy Plus, are as provided for in the State's Medicaid State Plan, Title 42 of the Code of Federal Regulations and Title XIX of the Social Security Act.
- C. X **Budget neutrality.** The Federal cost of services provided during the demonstration will be no more than 100 percent of the Federal cost to provide Medicaid services without the demonstration aggregate cap. The benefits and rights of the State plan eligibility groups are not altered via this demonstration. An Excel budget worksheet is provided that details the budget projections, including with and without waiver cost estimates, information about covered individuals, trend rate information, and includes a narrative description of the calculations.
- D. X **Public notice requirements.** The demonstration complies with public notice requirements as published in the Federal Register, Vol. 59, No. 186 dated September 29, 1994 (Document number 94-23960) and Centers for Medicare & Medicaid Service (CMS) requirements regarding Native American Tribe consultation.

III. STATE ONLY FUNDED PHARMACY PROGRAMS

The following information is provided for currently existing State only funded pharmacy programs. The item that applies is checked:

C. X **State Program Subsumed Into Demonstration.** A State only funded pharmacy program(s) named HMP / D currently exists, and it will be subsumed by the demonstration. Below are details about the current State only funded pharmacy program:

1. Income level ceiling. The income level ceiling for participation is 185 percent FPL.
2. Program eligibility characteristics. In addition to income ceiling, the program(s) eligibility parameters are X broad age and/or health conditions, narrow (such as limited to specific disabling conditions), or other (described):
3. Benefit coverage. The scope of benefits covered under the program(s) is: broad (all or most FDA approved drugs), X narrow (such as limited to drugs to treat specific health conditions), or other (described):
4. Enrollment figures. Currently there are 36,268 enrollees in the program(s).
5. Annual cost. Currently the program expenditures are \$20 million on an annual basis for the program(s).
6. X This proposed demonstration will be an expansion of coverage compared to the current State pharmacy program through:
 - a. X expanding the scope of coverage (e.g. prescriptions available);
 - b. X expanding the pharmacy services available (for example, via a pharmacy or nurse consultant that will provide additional management services);
 - c. X expanding the type and number of individuals eligible;
 - d. X expanding funding to assist with premiums and cost sharing;
By offering a voluntary mail order program
 - e. other (described):

B. **State Program Partially Subsumed Into Demonstration.** A State only funded pharmacy program(s) named currently exists, and will be **partially** subsumed by the demonstration. Below are details about the current State only funded program, and how this will interact with the demonstration:

1. Income level ceiling. The income level ceiling for participation is percent FPL.
2. Program eligibility characteristics. In addition to income ceiling, the program(s) eligibility parameters are broad, narrow, or other (described):
3. Benefit coverage. The scope of benefits covered under the program(s) is: broad, narrow, or other (described):
4. Enrollment figures. Currently there are enrollees in the program(s).

5. Annual cost. Currently the program expenditures are \$ _____ on an annual basis for the program(s).
6. Interaction with the demonstration. The State only funded program and the demonstration will operate simultaneously in the following manner (described):
7. _____ This proposed demonstration will be an expansion of coverage compared to the current State pharmacy program through:
 - a. _____ expanding the scope of coverage (e.g. prescriptions available);
 - b. _____ expanding the pharmacy services available (for example, via a pharmacy or nurse consultant that will provide additional management services));
 - c. _____ expanding the type and number of individuals eligible;
 - d. _____ expanding funding to assist with premiums and cost sharing;
 - e. _____ other (described):

D. X State Program Not Subsumed by Demonstration. A State only funded pharmacy program(s) named HMP currently exists, will not be subsumed by the demonstration, and will continue to operate during the Pharmacy Plus demonstration operation. The State has an approved 1115 waiver called HMP whereby individuals with incomes <300% FPL are eligible for a discount. The state will continue to pay 2% of these prescriptions.

D. _____ No State Funded Pharmacy Program Currently Exists. A State only funded pharmacy program does not exist in this State.

IV. PROGRAM ELEMENTS

Population to Whom Eligibility is Expanded via this Demonstration

E. Income Limit Criteria (the item that applies is checked):

1. ☐ The demonstration covers Medicare beneficiaries, whether or not they are eligible for Medicare Savings programs under Medicaid (e.g. QMBs and SLMBs) and/or people with a disability, who are not eligible for full Medicaid benefits, but whose incomes extend up to and including 200 percent of the Federal Poverty Level (FPL).
2. ☒ The demonstration covers Medicare beneficiaries, whether or not they are eligible for Medicare Savings programs under Medicaid (e.g. QMBs and SLMBs) and/or people with a disability, who are not eligible for full Medicaid benefits, but whose incomes are less than 200 percent of the FPL but extend up to and include 185 percent of FPL

3. ☒ Other (described): 1. Disabled adults 19 years of age and older.

F. Adults 62-65 years of age at <185% FPL.

G. Adults over 65 without Medicare.

H. Assets Test (the item that applies is checked):

I. ☐ There will be an assets tests performed. It is:

J. ☐ the same as Medicaid assets tests for the ☐ group

K. ☐ different from assets test in Medicaid (described):

2. ☒ There will not be an assets test.

L. Income Adjustments (the item that applies is checked):

M. ☐ There will be adjustments to income. They are:

N. ☐ the same as Medicaid income adjustments for the ☐ group

O. ☐ different from income adjustments in Medicaid (described):

P. ☒ There will not be adjustments to income.

Q. Individuals Eligible for the Demonstration. Table IV.1 below is filled out to indicate the groups of individuals who will be eligible for the demonstration.

Table IV.1 (all items that apply are completed)						
Eligibility Group Limited to Medicare beneficiaries and/or non-Medicare beneficiaries with a disability		Age Range (a)	FPL Range (b)	Medicare Beneficiaries ©	Non-Medicare Beneficiaries (d)	Specified Subset of Larger Groups (e)
1	Older Adults	62 and older	Up to 185%	X	X	N/A
2	Persons with Disabilities (Adults)	19 and older	Up to 185%	X	X	N/A
3	Persons with Disabilities (Children)	N/A	N/A	N/A	N/A	N/A

E. Enrollment Limit (the item that applies is checked):

1. ☒ Yes; number of enrollees _____ and how number derived (described):
The number of enrollees will be limited to the amount of state funds available.
2. ☐ No

F. Pharmacy Benefit Package (all items that apply are checked):

1. ☐ Since there will be coordination with private health insurance coverage, the services that enrollees receive will be those delivered through their own private health insurance. The demonstration will provide either assistance with private health insurance cost sharing or via the provision of wrap-around services only (see next section on coordination with private coverage).
2. ☐ The Pharmacy Plus demonstration pharmacy benefit will be the Medicaid State Plan benefit.
3. ☒ The Pharmacy Plus demonstration pharmacy benefit will be lesser in scope, as indicated below, than that provided under the current Medicaid State Plan benefit:
 - a. ☐ excludes or limits certain classes of drugs (described):
 - b. ☐ enacts a limitation on numbers or frequency of prescriptions that is not present in Medicaid or is more restrictive than Medicaid (described):
 - c. ☒ targets treatment of specific conditions consistent with program eligibility (described): diabetes, heart disease, high blood pressure, chronic lung disease (including emphysema and asthma), arthritis, anticoagulation, hyperlipidemia, incontinence, thyroid disease, osteoporosis, Parkinson's disease, glaucoma, multiple sclerosis, amyotrophic lateral sclerosis, cancer, and depression
 - d. ☐ other (described): A 20% co-pay will be required.
4. ☐ Other (described):

G. Pharmacy Benefit Management (all items that apply are checked):

Efficient and effective pharmacy benefit utilization via modern, private sector approaches is an important goal of the Pharmacy Plus Demonstration. Pharmacy Benefit Management is one way

to achieve the goal. The following will be used in the demonstration – their use may be expanded to the non-demonstration Medicaid program.

1. ☒ The demonstration will include the same benefit management approaches that ☒ are available, or ☒ will be available in Medicaid. For example, prior authorization procedures, formulary exclusions, a pharmacy benefit manager, etc. (described): Prior Authorization, Disease Management, Drug Utilization and Review, Preferred Drug List. 34 day supply for brand name drugs. Dose consolidation requirements, MMAC list, electronic cost avoidance at the point of purchase for those enrollees with T.P.L.
2. ☐ The demonstration will include different benefit management approaches than are available in Medicaid. These will be implemented to manage services for the expansion population only ☐; for the expansion and State plan population, but provider choice will not be restricted for the State plan population ☐; for the expansion and State plan population and provider choice will be restricted for the State plan population (a section 1115(a)(1) waiver of section 1902(a)(23) is requested in section VI below) ☐ (describe the affected State plan population):

Specific details and information are checked or provided here:

- a. ☐ pharmacy benefit manager (described):
 - b. ☐ prior authorization (described):
 - c. ☐ formulary or formulary exclusions (described):
 - d. ☐ other (described):
3. ☐ The demonstration will not include benefit management approaches. Benefit management ☐ is or ☐ is not included in non-demonstration Medicaid.
 4. ☐ other (described):

H. Coordination with Other Sources of Pharmacy Coverage – Private, State, and Medicare Plus Choice Plans

Coordination with and the financial support of other sources of health insurance is an important feature of the Pharmacy Plus Demonstration. It maintains the position of Medicaid as payor of last resort, provides incentive for enrollees' continued participation, and supports the maximization of participation in private insurance, employer sponsored insurance, COBRA, retirement health insurance plans, Medigap plans and Medicare Plus Choice plans. Pharmacy Plus works effectively with other Medicare pharmacy options.

The coordination and support can be:

- Actuarial equivalent payments to private carriers or to enrollees that are made on behalf of Pharmacy Plus enrollees – the payments made in lieu of the Pharmacy Plus program directly providing pharmacy coverage; and
- In the form of providing wraparound pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage.

In this demonstration, the following approaches will apply (all items that apply are checked):

1. ☐ Subsidies/cost sharing assistance for private health insurance coverage will be provided under the demonstration. The payment amount will reflect the scope and cost of pharmacy coverage in the private health insurance coverage and the cost of coverage in Pharmacy Plus, which includes enrollee cost sharing requirements. The process for the Subsidy will be described in the operational protocol and approval of the payment methodology and amount will be requested of CMS. Subsidies/incentives for enrollees to maintain coverage of the following will be provided including:
 - a. ☐ Private health insurance coverage (described):
 - b. ☐ Medigap (described):
 - c. ☐ Medicare endorsed pharmacy discount cards. The demonstration includes financial contribution towards the drugs purchased using the card (coordination with the card and contribution to the purchase are described):
 - d. ☐ other (described):
2. ☒ Pharmacy coverage will be provided to enhance other sources of pharmacy coverage, such as State programs, Medicare Plus Choice and private sources of coverage in a wraparound fashion in order to encourage participation in existing public and private sources of care (described):

3. ☒ Third party liability information will be gathered from enrollees and funds recovered.
4. ☐ Other (described):
5. ☐ Coordination with other sources of coverage is not part of this demonstration.

I. Primary Care Coverage and Related Medical Management (all items that apply are checked):

The demonstration includes a mechanism to ensure that demonstration enrollees utilizing services have coverage of basic primary care health services that will assist with medical management related to pharmacy products prescribed. This will take place in the demonstration in the following way:

1. ☒ Demonstration enrollees who have a source of coverage for primary care will not be provided primary care through the demonstration, but rather have services coordinated via medication management with the pharmacy benefit. Refer to Appendix A. Below is a description of how these benefits will be coordinated (described): Medication management reports will be provided quarterly to designated primary care providers.
2. ☒ Demonstration enrollees who do not have a source of primary care coverage will be provided services through the demonstration as follows:
 - a. ☐ The primary care services benefit will be the same as that in Medicaid (described):
 - b. ☐ The primary care benefit of _____ number of visits per _____, which entail the following services provided by _____ practitioners: _____.
 - c. ☒ Primary care access will be ensured by connecting clients to primary care sources for care (i.e. FQHCs/RHCs or Ryan White providers). Refer to Appendix A.
 - d. ☐ Other (described):
3. ☒ Coverage of primary care services will be attained by combining the above approaches. Refer to Appendix A. Above, both are checked and described, and each applied to the appropriate populations.
4. ☐ Other (described):

J. Premiums and Cost Sharing Information (all items that apply are checked):

Flexibility to include premiums and cost sharing, such as what may replicate that found in employer sponsored private health insurance coverage, is an important feature of the Pharmacy Plus Demonstration. Also, an important feature is design benefits that provide less first-dollar coverage in favor of protection against catastrophic drug costs. Enrollee cost sharing can be in the form of annual or monthly premium assessments, per-prescription copayment requirements, deductibles and coverage limits. It eases the challenge of operating budget neutral program and encourages personal independence since enrollees will remain involved in all facets of their health care, including financially.

1. ☒ The proposed program will include enrollee cost sharing (premiums, copayments, deductibles, etc.):
 - a. ☐ Premiums will be required (premiums are strongly suggested when including higher income categories):
 - i. ☐ Premiums are tiered or charged according to a sliding fee schedule that is ☐ attached or ☐ described below:
 - ii. ☐ Premiums are fixed in the amount of \$ ☐ per person on a ☐ monthly basis, ☐ annual basis, or ☐ other (described):
 - iii. ☐ Other (described):
 - b. ☒ Copayments:
 - i. in the amount of ☐ 20% ☐ per prescription or
 - ii. ☐ Beneficiaries will have different co-payments for single source, branded multi source, and generic drugs, according to the following schedule (described) :
 - iii. Brand name: \$ ☐ per prescription or ☐ percent of the cost.
 - iv. Branded multi-source: \$ ☐ per prescription or ☐ percent of the cost.
 - v. Generic: \$ ☐ per prescription or ☐ percent of the cost.

There will be a three-tiered co-payment structure: 1.) 20% per prescription for drugs for specific disease states and generic drugs; 2.) 10% per prescription with voluntary mail order program for these same drugs; 3.) After \$1,000 out of pocket expense, 20% co-payment for a broader range of eligible prescription drugs.
 - c. ☐ Deductibles (described):
 - d. ☐ Cost sharing requirements will vary with utilization (premiums, copayments, etc., other than deductibles):

- i. _____ Cost sharing amounts/requirements will decrease as individuals utilize more services (described):
 - ii. _____ Cost sharing amounts/requirements will increase as individuals utilize more services (described):
 - iii. _____ Other (described):
2. _____ The proposed program will not include enrollee cost sharing that differs from that in the Medicaid State Plan.
3. X The proposed program will include enrollee cost sharing stop-loss protections (describe): After the member has spent \$1,000 on eligible prescription drugs, the member will be eligible for a 20% co-payment for all eligible prescription drugs, regardless of disease category.
4. _____ Other (described):

K. The Demonstration will Deliver Services in the Following Manner (all items that apply are checked):

1. _____ Services will be delivered through private health insurance coverage.
2. _____ Services will be delivered Fee-for-Service through this demonstration.
3. _____ Services will be delivered via a system other than Fee-for-Service through this demonstration (described):
4. X Services will be delivered through this demonstration via the same network of providers that deliver comparable services to Medicaid beneficiaries.
5. _____ Services will be delivered through this demonstration via a subset of providers that deliver services to Medicaid beneficiaries.
6. _____ Services will not be delivered via providers that serve Medicaid beneficiaries. The demonstration providers will be _____, and these providers will be selected provide services under the demonstration utilizing a _____ procurement process.
7. _____ Other (described):

V. BUDGET NEUTRALITY

The Federal costs of services provided during the demonstration will be no more than 100 percent of the cost to provide Medicaid services without the demonstration. A new population that would otherwise not be eligible for Medicaid will be able to obtain prescription drugs paid for by Medicaid. While the demonstration includes individuals who are not currently eligible for Medicaid, this new population could become eligible for Medicaid through deterioration in their health status and reduced income due to high medical expenses. The demonstration is intended to reduce the costs the State incurs for State plan eligible groups through lessened service utilization, reduced period of Medicaid eligibility, and more effective pharmacy benefit management. Federal payments will be provided for the Pharmacy Plus costs incurred for the new population to the extent that Federal Medicaid payments to the State do not exceed what would otherwise be paid.

The attached budget shell relies upon a credible methodology that will assure savings in the Medicaid program that would not have occurred in the absence of the demonstration. When a Pharmacy Plus demonstration is entirely or partially subsuming a State-only funded pharmacy program, the State must provide documentation as to how Medicaid expenditures will be reduced under the demonstration (compared to the “without demonstration” levels) and how budget neutrality will be achieved. For example, the expenditures that are saved from a reduction in the number of eligibles who would have been in the Medicaid program if no demonstration existed, are then available to pay for the extension of pharmacy coverage for the new demonstration population. The attached budget shell _____ was used in the development of budget neutrality.

The State Plan eligible groups that are the source of savings are included in budget neutrality. This is considered an impacted population. However, the benefits and rights of the existing Medicaid eligibility groups themselves are not altered via the demonstration. This means, in part, that cutbacks in eligibility for existing Medicaid eligibility groups covered under the State’s Medicaid Plan will not be recognized as a source of savings in this template for purposes of meeting budget neutrality in any proposed expansion demonstration. Savings that do not limit eligibility but are achieved through better management of pharmacy services to existing Medicaid populations may be considered in the budget neutrality calculations.

The terms and conditions of demonstration award will specify the aggregate financial ceiling on Federal financial payments for services included in the budget neutrality agreement. Under the aggregate ceiling methodology the State and Federal authorities must reach agreement prior to demonstration approval on cost and eligibility trend rates. The trend rates will then be in place in the budget ceiling during the demonstration.

A. Impacted Budget Neutrality Population. Table V.1 below is filled out to

indicate the Medicaid population that is the impacted budget neutrality population.

Table V.1 (check all groups that apply):				
Population	All (1)	Institutionalized (2)	Community Dwelling (3)	Other (described): (4)
Aged				
Blind/Disabled Adults				
Blind/Disabled non- Adults				

A. Costs. The State estimates the services cost of this program will be \$_____ over its _____ year demonstration period.

Refer to attached Excel spreadsheet for details.

VI. EXPENDITURE AUTHORITY

The Following Authority is Needed for this Demonstration Under Costs not Otherwise Matchable (item is checked to verify the request):

- A. _____ Section 1115(a)(1) authority of the Social Security Act is requested to enable the State to restrict freedom of choice of provider through a method such as Pharmacy Benefit Management.
- B. X Section 1115(a)(2) authority of the Social Security Act is requested for the following expenditures to be made under the HMP demonstration (which are not otherwise included as expenditures under section 1903) for the period of the demonstration to be regarded as expenditures under the Title XIX program:

Expenditures for extending pharmacy benefits and _____ for _____ individuals _____ at or below 185% percent of the Federal Poverty Level (FPL) who are Medicare eligible, or people with a disability, who are not also Medicaid eligible except for Medicaid coverage of Medicare premiums or cost sharing.

In addition, the following will not be applicable in this demonstration:

- *Premiums and Cost Sharing under Section 1916:* To permit fixed premiums, and cost sharing that is more than nominal, to be imposed on and collected from demonstration participants.
- *Amount Duration and Scope of Services under Section 1902(a)(10)(B):* To permit the State to offer demonstration participants benefits that are not equal in amount, duration and scope to other Medicaid beneficiaries.
- *Retroactive Eligibility under Section 1902(a)(34):* To permit the State not to offer demonstration participants retroactive eligibility.
- *Premiums under Section 1902(a)(14):* To permit the State to impose on and collect premiums from demonstration participants in excess of those that would be permitted under section 1916.

VII. ADDITIONAL REQUIREMENTS

In addition to the above requirements, the State agrees to the Pharmacy Plus Model Special Terms and Conditions (STCs) of Approval, and agrees to prepare the Operational Protocol document as described in the Model STCs. During CMS's review and consideration of this demonstration request, using the Model STCs, we will work with CMS to develop STCs that are specific to this request that would become part of the approval of demonstration authority.

Date

Name of Authorizing Official, Typed

Name of Authorizing Official, Signed

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Appendix

Centers for Medicare & Medicaid Services Guidelines for Coordinated Primary Care

Primary Care Requirements – For this demonstration, Centers for Medicare & Medicaid Services (CMS) requires states to ensure access to primary care services. States can fulfill this requirement by actually providing a primary care benefit package, by connecting clients to FQHCs/RHCs or Ryan White primary care providers, for primary care services, or, if an individual has primary care coverage (for example, via Medicare), CMS requires coordination via medical management of the pharmaceutical benefit. Medication management could be arranged via case management (delivered by appropriately qualified staff) or via specialty services such as nursing or home health, or coordinated via an enhancement to the Drug Utilization Review system that will allow the State to perform medication management services. Details of this coordination are included in the Pharmacy Plus application.

If a state chooses to connect clients to FQHCs/RHCs or Ryan White providers, then it must meet the criteria listed below. Although Ryan White providers are not mentioned below, include descriptions of corresponding coordination activities as listed below where applicable.

1. States must work with their Primary Care Associations to facilitate access to primary care services and must provide CMS with a letter based on the discussions that indicates the Primary Care Association's understanding and support of the process for enrolling participants to FQHCs (RHCs) for primary care services.
2. The State must verify that the FQHCs have the capability to serve this population. They must also provide a copy of the geographic breakdown of FQHCs in order to assure that there is adequate access to FQHCs.
3. Any written materials that pharmacy providers or the state supplies to clients must include information on how to access primary care services at FQHCs. These materials must include a list of primary care providers (FQHCs), their locations, and phone numbers. States must provide a copy of these materials to CMS.
4. Any oral counseling that the pharmacy clients receive must include an explanation of how they may access primary care services at their nearest FQHC, and provide the location and phone number of the nearest facilities. The State must describe how this requirement will be fulfilled.
5. The State must provide an explanation of how they will evaluate or assess the impact of providing referrals for primary care services. For example, any focus groups or surveys of the clients must include a component that looks at this feature of the program.